UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

In re: Oral Phenylephrine Marketing and Sales Practices Litigation This document relates to: All actions.	Case No. 1:23-md-03089-BMC

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE INITIAL STREAMLINED CONSOLIDATED NEW YORK BELLWETHER CLASS ACTION COMPLAINT

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The parties agree that the FDA has for decades deemed phenylephrine an effective decongestant and that federal law requires Defendants to say their medicines are "nasal decongestant[s]." *See* Opp. at 9. Plaintiffs cabin their claims to "challeng[ing] only the *indications* section" of Defendants' labels, *id.* at 4, and try to save those claims from preemption by arguing that federal law requires Defendants to "correct their labels" to say that phenylephrine is ineffective, *id.* at 2. They are wrong. Plaintiffs rely on cases involving personal injury claims and different regulations that permit label updates to address new safety concerns. But this is not a safety case; it is an efficacy case, and the regulations are different. No law allows anyone else's judgment to be substituted for the FDA's conclusion that phenylephrine is effective. Plaintiffs identify no case where state law or RICO claims displaced an FDA efficacy determination. Instead, the CARES Act—which the Opposition ignores—empowers the FDA alone to determine whether changes are warranted to efficacy findings reflected in a monograph.

I. Plaintiffs' State-Law Claims Are Expressly Preempted.

A. Defendants Cannot Unilaterally Change FDA-Approved Indications for Use.

Federal law expressly preempts state-law requirements that are "different from or in addition to, or that [are] otherwise not identical with" federal law. 21 U.S.C. § 379r(a)(1). That is true for *all* over-the-counter ("OTC") drugs, whether marketed under a monograph or an NDA. *Id.*[1] Plaintiffs argue that their state-law claims parallel federal law and are not preempted because the monograph directs Defendants to pick a required indication "as appropriate" and permits "[o]ther truthful and nonmisleading statements." Opp. at 4 (citing 21 C.F.R. § 341.80(b)). Plaintiffs

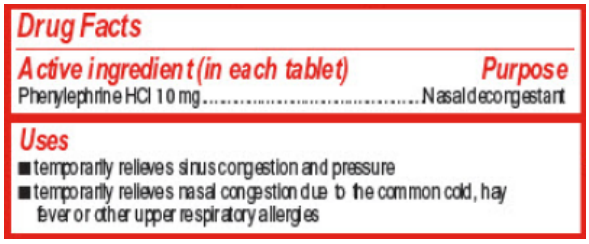
[1] Plaintiffs claim "Defendants make *no* argument regarding preemption of OTC drugs approved under an NDA." Opp. at 7. But the analysis is the same. *See Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 786, 793 (E.D. Tex. 2008) (efficacy claims preempted since "NDA approval process establishes a federal requirement for drug labeling under Section 379r"); *Smith v. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC*, 660 F. Supp. 3d 863, 873 (N.D. Cal. 2023).

say these regulations require Defendants to state that phenylephrine is not effective. Not so.

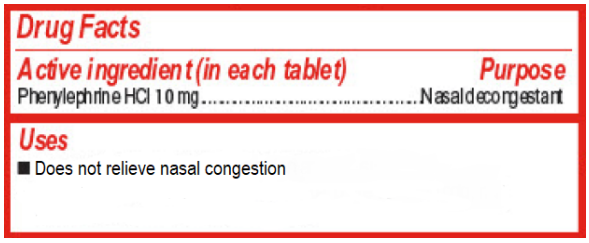
The monograph states: "Other truthful and nonmisleading statements, *describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section*, may also be used." 21 C.F.R. § 341.80(b) (emphasis added). The FDA gave manufacturers this flexibility because "there may be many ways of fairly and accurately stating *the same information*." 51 Fed. Reg. 16,258, 16,261 (May 1, 1986) (emphasis added). Companies can, for example, "provide for regional differences in the way people refer to the same condition, e.g., acid stomach versus upset stomach." *Id.* at 16,258. But "the monograph language" is the FDA's "standard in determining whether alternative statements are accurate or require regulatory action." *Id.* at 16,259. Alternative language must "not be inconsistent with that [product's] indication for use." 50 Fed. Reg. 15,810, 15,813 (April 22, 1985). The monograph's directive to pick an indication "as appropriate" does not permit Defendants to trade the one phrase ("temporarily relieves nasal congestion") for its opposite ("does not temporarily relieve nasal congestion"). The same is true as to Plaintiffs' flawed reading of 21 C.F.R. § 330.1(c)(2), which permits "alternative truthful and nonmisleading statements describing only those indications for use that have been *established in an applicable monograph*." *Id.* (emphasis added).

Plaintiffs also admit that federal law "requires manufacturers to include verbatim the 'exact language' in the monograph" when it comes to the statement of identity. Opp. at 4. Here, that monograph language is "nasal decongestant." 21 C.F.R. § 341.80(a). Plaintiffs "do not challenge" this language. Opp. at 10. But in the next breath, they argue that Defendants *must* say that "their drugs do not work." *Id.* That makes no sense. Plaintiffs' theory would hopelessly confuse consumers by requiring Defendants' labels to simultaneously say that phenylephrine is a nasal decongestant and that it does not decongest. Here is what that would look like:

Example of current label (ECF No. 200-9)



Plaintiffs' proposed label



Section 379r was designed to avoid the consumer confusion Plaintiffs' position would cause. *See* Mem. at 19-20. Defendants' labels are what federal law requires. The monograph directs Defendants to "[s]elect one of the following" phrases to include on the label: "[f]or the temporary relief of nasal congestion," or "[t]emporarily relieves nasal congestion." 21 C.F.R. § 341.80(b)(1). It also gives the option of including additional language, such as "[f]or the temporary relief of [a] stuffy nose." *Id.* § 341.80(b)(2). Defendants' labels comply with these requirements. As a result, Plaintiffs' assertion that "some other terminology is necessary to ensure that the label is not misleading" is preempted by Section 379r. *Novotney v. Walgreen Co.*, 683 F. Supp. 3d 785, 792 (N.D. Ill. 2023); *see also* Mem. at 14-16 (collecting cases).

Nor are Plaintiffs correct that the general misbranding statute, 21 U.S.C. § 352, imposes "an independent obligation" that defeats preemption. Opp. at 10. The Second Circuit has rejected that argument in the context of a substantively identical FDCA cosmetics preemption provision. The misbranding statute cannot be used "to impose such *additional* labeling requirements" because to do so "would be construing state law to impose many 'requirements' that are not contained in the federal statute, or in the regulations issued thereunder." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 38 (2d Cir. 2020); *see also* Mem. at 16-17 (collecting cases). That is because "[t]he [FDA] regulations have . . . stated, with specificity, what information is necessary to avoid misleading consumers." *Critcher*, 959 F.3d at 38. The FDA agrees. "A manufacturer that elects to use the exact wording of the monograph"—as Defendants have done—"would be assured that FDA agrees

that such labeling is appropriate." 50 Fed. Reg. at 15,813. That is because "labeling established in an OTC drug monograph . . . represent[s] the agency's determination, following extensive notice and comment rulemaking, of the specific indications for which an OTC drug product would be generally recognized as safe and effective, *and not misbranded*." *Id.* at 15,812 (emphasis added); *see also Youngblood v. CVS Pharmacy*, 2021 WL 3700256, at *3 (C.D. Cal. Aug. 17, 2021) ("products complying with the labeling requirements of the [monograph] are not misbranded" (cleaned up)); *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Pracs. Litig.*, 701 F. Supp. 2d 356, 362 (E.D.N.Y. 2010) (manufacturers can "rely on the FDA monograph").

B. Plaintiffs Misplace Reliance on Safety Cases and Different Regulations.

This is an efficacy case, not a safety case. Plaintiffs' inefficacy allegations are "diametrically opposed" to the FDA's decades-old conclusion otherwise. *Mills*, 581 F. Supp. 2d at 789. And while many of Plaintiffs' cases involved regulatory regimes permitting manufacturers to unilaterally change safety warnings, no comparable law permits Defendants to change efficacy indications as Plaintiffs propose here.

These distinctions make this case different from all of the cases cited by Plaintiffs, none of which allowed a plaintiff to use state law to challenge FDA efficacy determinations. For example, Plaintiffs cite numerous inapposite Supreme Court cases regarding the implied preemption analysis for *safety warnings on prescription drugs* in *personal injury cases*. *See Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Wyeth v. Levine*, 555 U.S. 555 (2009). Unlike Section 379r, "Congress has not enacted [an express preemption] provision for prescription drugs." *Wyeth*, 555 U.S. at 574. Despite this, Plaintiffs argue that their "claims are not preempted unless Defendants show they 'fully informed the FDA' of the need for a label change and 'the FDA, in turn, informed [them] that the FDA would not approve changing [their PE] drug's label.'" Opp. at 10 (citing *Albrecht*, 587 U.S. at 314). But that

is an impossibility preemption analysis. It is irrelevant to express preemption, where Section 379r prohibits claims that impose requirements "different from or in addition to, or . . . otherwise not identical with" FDA requirements, such as inconsistent efficacy statements. Moreover, the regulatory regime in these cases permitted prescription drug manufacturers to "unilaterally strengthen [their] warning[s]." *Wyeth*, 555 U.S. at 573; *see also Albrecht*, 587 U.S. at 314-15 (discussing "FDA regulations" about "drug safety"); *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 42 (2011) (prescription drug regulation, 21 C.F.R. § 201.80, required update to "include a warning" based on new safety information). No comparable regulation exists for OTC monograph drugs, and departing from the monograph is a violation of federal law. Mem. at 18.

Plaintiffs' reliance on safety-related OTC drug cases is similarly unavailing. The plaintiffs in *In re Acetaminophen ASD-ADHD Prods. Liab. Litig.*, 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022), brought personal-injury claims exempted from express preemption by Section 379r(e), so the decision turned on implied preemption and whether the monograph permitted the defendant to "unilaterally strengthen[] [safety] warnings on its label." *Id*. at *7. Likewise, *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1284 (S.D. Fla. 2021), allowed a parallel misbranding claim that alleged the absence of adequate safety warnings for a drug not covered by a monograph, finding the defendants "*can* change a label" to strengthen safety warnings. *Id.* at 1304. The *Zantac* theory is not viable for a monograph product, which the FDA has already deemed *not* misbranded when the label includes the authorized language, and it is not viable in an efficacy case because Defendants cannot unilaterally change efficacy statements.

C. Plaintiffs' Attempt to Save Some Claims from Preemption Is Unavailing.

Express warranty claims are not "product liability" claims saved from preemption by 21 U.S.C. § 379r(e). *See* Opp. at 13-14. Courts routinely hold that warranty claims seeking "purely economic injury" are preempted. *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 113 n.7

(S.D.N.Y. 2022); *see also, e.g.*, *Singo v. Ricola USA, Inc.*, 2024 WL 196709, at *5 (S.D.N.Y. Jan. 18, 2024) (Section 379r preempts New York warranty claims). That is because "'product liability' actions do not include those for pure economic loss, as those fall more into the realm of contract law." *Goldstein*, 637 F. Supp. 3d at 113 n.7. Plaintiffs do not cite a single case extending Section 379r(e) to economic loss claims.

The Opposition's passing references to certain advertising-related statements not expressly listed in the monograph likewise do not survive preemption. *See* Opp. at 14. While the Complaint briefly challenges certain "maximum strength" and "severe" statements, these representations are allegedly false only because "the products hav[e] no efficacy at all." Compl. ¶ 70. Plaintiffs' other advertising claims depend on similar efficacy statements that are consistent with the monograph's efficacy findings. *See id.* ¶ 145 (challenging "promise[] to relieve 'Nasal Congestion' and 'Sinus Pressure'"), ¶ 168 (similar), ¶ 451 (arguing Defendants could have "disclosed the truth about PE"). These claims are preempted because Section 379r preempts "state-law advertising claims, provided the advertisements are based upon content approved by the FDA for a drug's labeling." *Zantac*, 512 F. Supp. 3d 1278, 1296 (S.D. Fla. 2021); *see also Smith*, 660 F. Supp. 3d at 873 (efficacy claims challenging advertising "materially identical" to FDA-approved label were preempted); Mem. at 15-16 (collecting cases).

II. Plaintiffs' State-Law Claims Conflict with Federal Law and Are Preempted.

A. It Is Impossible for Defendants to Comply with Their Federal Obligations and the State Law Duties Plaintiffs Seek to Impose.

Plaintiffs' argument that Defendants can comply with both federal and state law largely duplicates the same incorrect theory underlying their express preemption arguments: that Defendants could "unilaterally" change their labels to contradict the monograph. Opp. at 14-16. Defendants cannot do so. *Supra* § I.A. Plaintiffs' cases all involve whether manufacturers can add

new safety warnings beyond those already approved by the FDA. *See Wyeth*, 555 U.S. at 569-71 (regulation allowed manufacturer to add stronger *safety warning* to label on basis of safety risks); *Acetaminophen*, 2022 WL 17348351, at *7-9 (same to update "safety warnings" on label); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 144 F. Supp. 3d 699, 730 (E.D. Pa. 2015) (same to address "serious health problems"). Those cases say nothing about efficacy statements for monograph drugs. *Supra* § I.A.; Mem. at 3, 18.

Plaintiffs also suggest that Defendants could "stop selling" phenylephrine products to avoid a conflict. Opp. at 16. The Supreme Court has squarely rejected this kind of "stop-selling" argument as "incoheren[t]." *Bartlett*, 570 U.S. at 488. And the *Bartlett* stop-selling dicta that Plaintiffs rely on, *see* Opp. at 16, is limited to "design-defect claims" alleging a drug is "dangerous to health," which are not asserted here. *Bartlett*, 570 U.S. at 487 n.4; *see also In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015) (possible exception recognized in *Bartlett's* footnote 4 applies only to "'pure' design defect claims"). Courts consistently hold that allegations of ineffectiveness cannot force a manufacturer to stop selling medicine that the FDA has deemed effective. Mem. at 19 (collecting cases); *see also Mills*, 581 F. Supp. 2d at 790 (preempting efficacy claims).

B. Plaintiffs' State-Law Claims Impose Obstacles to Congress's Purposes.

Plaintiffs cannot dispute that the FDCA was designed to create a "uniform—and federally-led—regulatory scheme" for OTC drugs. *See Critcher*, 959 F.3d at 38. Plaintiffs instead rely—again—on *Wyeth* and this Court's discussion of that case in *Bayer* to oppose obstacle preemption. Opp. at 16-17. But *Wyeth* rejected obstacle preemption based on the rationale that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision." *Wyeth*, 555 U.S. at 574. Unlike in *Wyeth*, Congress did so here. 21 U.S.C. § 379r. That "is powerful evidence" that Congress intended "FDA oversight to be the exclusive

means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575.

The recent CARES Act amendments to the monograph process reaffirm Congress's intent to preclude state-law challenges to FDA efficacy determinations. There, Congress confirmed that an OTC drug is "recognized as . . . effective" if it complies with the monograph, as Defendants' drugs do here. 21 U.S.C. § 355h(a)(1). The FDA subsequently promulgated a post-CARES Act administrative order confirming that phenylephrine remains effective. *See* Final Administrative Order (OTC000026) §§ M012.1, M012.20(a) (Oct. 14, 2022), *available at*: https://tinyurl.com/2mmz7y9h. Congress further created an administrative order process by which changes to the monograph could be made by the FDA acting under the HHS Secretary. *See* 21 U.S.C. § 355h(b)(1). That process empowers only "[t]he Secretary"—not individual states or lay juries—to determine when monograph drugs are "effective." *Id.* § 355h(b)(1)(C). That Congress gave manufacturers authority to make "[m]inor changes in the dosage form of a drug" without seeking prior FDA approval, *see id.* § 355h(c)(1), confirms Congress knew how to authorize deviations from the monograph. Congress did not do so for a drug's efficacy statements.

Allowing Plaintiffs' claims to proceed would undermine the uniform regulatory regime that Congress intended to protect. *See* Mem. at 19-20. Plaintiffs do not cite any case where a court allowed a jury to second-guess an FDA efficacy finding. This Court should not do so either.

III. The RICO Claim Fails for at Least Two Independent Reasons.

A. The Indirect Purchaser Rule Bars Plaintiffs' RICO Claim.

Plaintiffs cite no case finding the indirect purchaser rule inapplicable to RICO claims. That is because "[e]very circuit to have considered the issue has held that the rule also applies to civil RICO actions." *Humana, Inc. v. Biogen, Inc.*, 666 F. Supp. 3d 135, 141 (D. Mass. 2023).

The primary cases Plaintiffs rely upon do not even discuss the indirect purchaser rule, much less reject it. The Supreme Court's reasoning in *Bridge v. Phoenix Bond & Indemnity Co.*, 553

U.S. 639 (2008) (and other cases) "all but dictates that the [indirect purchaser rule] applies" to RICO claims. *United Healthcare Servs., Inc. v. United Therapeutics Corp.*, 2024 WL 1256266, at *9 (D. Md. Mar. 25, 2024). "*Bridge* . . . does not stand for the proposition that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule." *In re Insulin Pricing Litig.*, 2019 WL 643709, at *11 (D.N.J. Feb 15, 2019). As to *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479 (1985), that case "has no bearing on whether the indirect purchaser rule applies equally in the RICO context," "does not at all mention the indirect purchaser rule," and does not "provide any analysis tending to suggest a preference that such [a] rule not be applied in the RICO context." *In re Revlimid & Thalomid Purchaser Antitrust Litig.*, 2024 WL 2861865, at *35 (D.N.J. June 6, 2024); *see also Zantac*, 546 F. Supp. 3d 1216, 1224-25 (S.D. Fla. 2021) (same).

The Second Circuit cases cited by Plaintiffs are also off-base. *Horn v. Medical Marijuana* addressed whether an antecedent personal injury is a barrier to RICO standing and reaffirmed that "cases concerning antitrust standing inform our interpretation" of RICO standing. 80 F.4th 130, 135-38 (2d Cir. 2023). And *Alix v. McKinsey & Co.* was a competitor dispute that turned on issues of proximate causation; it has nothing to do with RICO standing. 23 F.4th 196, 206 (2d Cir. 2022).

B. The RICO Claim Is Precluded by the FDCA.

Plaintiffs are wrong to argue that *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014) and *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48 (2d Cir. 2016), reject Defendants' preclusion argument. Opp. at 22. *POM Wonderful* did not involve a challenge to the *factual accuracy* of the label—the case was about whether the product package as a whole misled consumers about the primary juices in the product—much less a challenge that was inconsistent with an FDA determination. 573 U.S. at 110. In other words, it was "not a case where a lawsuit is undermining an agency judgment" and it did not involve a challenge to "drug labels" that are "preapprove[d] . . . under [FDA] regulations." *Id.* at 116, 120. The opposite is true here.

The RICO claim *depends* on the theory that the FDA's finding that "phenylephrine works as a nasal decongestant" is wrong. Compl. ¶ 475. Where *there is a conflict* between implementation of the FDCA and another federal statute, the "greater specificity" of FDA regulations "matter[s]" for purposes of preclusion. *POM Wonderful*, 573 U.S. at 118. As to *Church & Dwight*, the Lanham Act claims there were not precluded because they did not challenge the FDA's accuracy determinations, only whether the FDA had correctly determined the propensity of an accurate label to nevertheless mislead consumers. 843 F.3d at 64. The Second Circuit distinguished that claim from ones like those here, which involve "the truth or falsity of an FDA-approved factual assertion about the *effects* of a medical product." *Id.* at 73 n.13 (emphasis added). Such claims are precluded. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63-64 (2d Cir. 2016); *Church & Dwight*, 843 F.3d at 73 n.13 ("deference to [FDA's] determination of truthfulness" warranted in *Apotex* because FDA "had expertise in the matter and had devoted exhaustive process to the inquiry").

Plaintiffs also exclusively rely on Lanham Act preclusion cases. But in that context, the preclusion analysis is sensitive to the fact that "Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling." *POM Wonderful*, 573 U.S. at 119; *Church & Dwight*, 843 F.3d at 65 (those statutes "serve distinct and complementary purposes"). The same is not true for the FDCA's drug labeling requirements and RICO. That is why "[c]ourts in this Circuit have routinely precluded RICO claims where the alleged conduct is already covered by a more detailed federal statute." *Palmer v. Trump Model Mgmt., LLC*, 175 F. Supp. 3d 103, 109 & n.14 (S.D.N.Y. 2016) (collecting cases). This Court should do the same.

* * *

This Court should dismiss the Initial Streamlined Complaint with prejudice.

August 5, 2024

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